

פברואר 2024

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,הריני להודיעכם כי היה עדכון בעלון של התכשיר:**ספייק-וקס 0.2 מ"ג/מ"ל Spikevax 0.2 mg/mL****Dispersion for injection****Active ingredient and its quantity:****החומר הפעיל וכמותו:**elasomerane 1.26 mg/vial
mRNA Vaccine encoding the SARS-CoV-2 spike protein**התוויה:**

Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

להלן העדכון בעלון לרופא:

4.4. Special warnings and precautions for useCapillary leak syndrome flare-ups

A few cases of capillary leak syndrome (CLS) flare-ups have been reported in the first days after vaccination with Spikevax. Healthcare professionals should be aware of signs and symptoms of CLS to promptly recognise and treat the condition. In individuals with a medical history of CLS, planning of vaccination should be made in collaboration with appropriate medical experts

Immunocompromised individuals

~~The efficacy of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy and may be lower.~~

~~The recommendation to consider a third dose in severely immunocompromised individuals (see section 4.2) is based on limited serological evidence with individuals who are immunocompromised after solid organ transplantation.~~

4.8. Undesirable effects

[...]

Spikevax (original) in solid organ transplant recipients

The safety, reactogenicity, and immunogenicity of Spikevax (original) were evaluated in a two-part Phase 3b open-label study in adult solid organ transplant (SOT) recipients, including kidney and liver transplants (mRNA-1273-P304). A 100 microgram (0.5 mL) dose was administered, which was the dose authorised at the time of study conduct.

In Part A, 128 SOT recipients received a third dose of Spikevax (original). In Part B, 159 SOT recipients received a booster dose at least 4 months after the last dose (fourth dose for mRNA vaccines and third dose for non-mRNA vaccines).

Reactogenicity was consistent with the known profile of Spikevax (original). There were no unexpected safety findings.

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5.1. Pharmacodynamic properties

[...]

Immunogenicity in solid organ transplant recipients

The safety, reactogenicity, and immunogenicity of Spikevax (original) were evaluated in a two-part Phase 3b open-label study in adult solid organ transplant (SOT) recipients, including kidney and liver transplants (mRNA-1273-P304). A 100 microgram (0.5 mL) dose was administered, which was the dose authorised at the time of study conduct.

In Part A, 128 SOT recipients received a third dose of Spikevax (original). In Part B, 159 SOT recipients received a booster dose at least 4 months after the last dose.

Immunogenicity in the study was assessed by measurement of neutralising antibodies against pseudovirus expressing the ancestral SARS-CoV-2 (D614G) strain at 1 month after Dose 2, Dose 3, booster dose and up to 12 months from the last dose in Part A, and up to 6 months from booster dose in Part B.

Three doses of Spikevax (original) induced enhanced neutralising antibody titres compared to pre-dose 1 and post-dose 2. A higher proportion of SOT participants who had received three doses achieved seroresponse compared to participants who had received two doses. The neutralising antibody levels observed in SOT liver participants who had received three doses was comparable to the post-dose 2 responses observed in the immunocompetent, baseline SARS-CoV-2-negative adult participants. The neutralising antibody responses continued to be numerically lower post-dose 3 in SOT kidney participants compared to SOT liver participants. The neutralising levels observed one

month after Dose 3 persisted through six months with antibody levels maintained at 26-fold higher and seroresponse rate at 67% compared to baseline.

A fourth (booster) dose of Spikevax (original) enhanced neutralising antibody response in SOT participants compared to post-dose 3, regardless of the previous vaccines received [mRNA-1273 (Moderna), BNT162b2 or any mRNA-containing combination]; however, SOT kidney participants had numerically lower neutralising antibody responses compared to SOT liver participants.

בעלון לצרכן לא היו שינויים.

בברכה,

מדיסון פארמה בע"מ